UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,272	02/06/2002	H. Andrew Strong	273012012500	1974

7590 07/28/2004

Kawai Lau
Morrison & Foerster LLP
Suite 500
3811 Valley Centre Drive
San Diego, CA 92130-2332

EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,272	STRONG ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on May 10, 2004 has been entered. Claims 1-2, 5-19 are under consideration as they read on the elected species. Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendment.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2, 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy.

Levy discloses treating choroidal neovasuclar (CNV) lesions by photodynamic therapy comprising administering green porphyrin such as BPD-MA to patients in need thereof. (see abstract; col 3, lines 25-50). Levy discloses small lesions of at 2 or 3 which is construed to meet the limitations of the instant claims 4-5. (see table 7, col 13). Levy also discloses administration of green porphyrins at the doses of 0.1-20 mg/kg which falls within the ranges instantly claimed.[1]

Levy also teaches administering liposomal forms of BPD-MA, visible light spectra of about 50-100 Joules/cm2, and does of about 0.1-20 mg/kg which meet the limitation of the instant claims 14-19.

Levy fails to specifically disclose the subject's lesion size or visual acuity of subject at baseline to be less than 65 letters. Levy also lacks the explicit

[1] Note that the Drug Facts and Comparison provided in the previous Office Action describe a methodology for measuring body surface area ("BSA") in m2. Accordingly, a 70 kg, 180 cm individual would have roughly a BSA of 1.9 m2. Thus, a

teaching for coupling a ligand to his BPD-MA. However, Levy teaches that green porphyrin may be coupled with a target-specific ligand such as antibody or immunologically active fragment (see col 3, lines 60-66).

Thus, first it would have been obvious to one of ordinary skill in the art at the time of invention to determine by routine experimentation what type CNV lesions size would best benefit from Levy's method, or even characterize what type of patient population, based on their visual acuity, would best benefit from Levy's methods. Second, it would have been obvious to one of ordinary skill in the art at the time of invention to couple a specific ligand to the BPD-MA of Levy, because as suggested by Levy, himself, the ordinary skill in the art would have had a reasonable expectation of success in improving the outcome of the photodynamic therapy.

Response to Arguments

Applicant's arguments filed May 10, 2004 have been fully considered but they are not persuasive. Applicant argues that Levy does not teach the visual acuity of the subjects or lesion size prior to PDT.

As the initial matter, Levy discloses CNV lesions within the definition of the instant occult CNV. Levy discloses treating lesions characterized by neovascularization caused by age-related degeneration (AMD). (col 5, lines 35-line 41; col 15, line 33-col 16, line 20). Such lesions encompass the instant limitation of "occult CNV."

0.21 mg/kg dosing of Levy is the same as 7.8 mg/m2 dosing of the instant method. Therefore, Levy anticipates the dosing limitations of the instant claims.

Further, Levy provides ample evidence for effectiveness of Photodynamic therapy (PDT) in treating different type of lesions by their histological grading. (see col 13, lines 1-67). Table 7 of Levy provides adequate guidance as to the type of lesions that are treated by Levy's methods. Accordingly, determining the optimal lesion size that would benefit from Levy's methodology would have been obvious.

The question of whether a particular parameter can be optimized or not is addressed in *In re Antoine*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Accordingly, the controlling question is simply whether the differences between the prior art and the claimed invention as a whole are such that the claimed invention as a whole would have been obvious. *Id.* at 8. In the instant case, Levy clearly provides that optimal clinical efficacy is a function of "lesion histology," "duration of treatment," and "the dose of the dye employed." (see table 2-6). Levy provides for effectiveness of PDT for treating different types of CNV. Levy further determines the size and type of lesions best treated by his methods and identifies potential candidates. Accordingly, maximizing the efficacy of his therapy based on such parameters would have been a matter of routine experimentation.

Note that Examiner does not argue that it would have been obvious for one of ordinary skill in the art to try varying every parameter of the therapy taught by Levy in order to optimize the effectiveness of the therapy. Rather, those parameters that are clearly established by Levy and the art to affected the clinical result. In the instant case, size and type of lesions or their visual acuity are such

parameters that would determine the type of candidates able to benefit from Levy's methods.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

ss